

ABSTRACT OF THE DISCLOSURE

A method of performing interactive clinical trials for testing a new drug comprising performing a pre-clinical phase in which a computer model for pharmacokinetics and pharmacodynamics of the drug is created and adjusted based on in vitro studies and in vivo studies in animals. A phase I clinical research is performed in which a clinical trial on at least a single dose is performed in parallel with performing computer simulation studies using the computer model. The computer model is adjusted based on comparison of the results of the clinical research and the computer simulation. A maximal tolerated dose, minimum effective dose, and a recommended dose is determined based on the phase I clinical research in conjunction with the computer simulations. The drug is checked for cumulative effects and providing this information to the computer model. Multiple simulations are performed using the computer model with different doses and dosing intervals. An optimal protocol is determined for the most responsive patient populations and indications for a phase II clinical trial. Phase II clinical trial is performed where a number of small scale clinical trials are performed in parallel based on results of the above. The interim results are analyzed to choose the most promising regimens for continued clinical trials. Phase III clinical research is performed for chosen indications by chosen protocols. Phase IV studies are performed for post-marketing subpopulation analysis and long term product safety assessment.